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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,493	07/23/2003	William E. Rich	016866-009520US	1999

20350 7590 08/24/2007

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
08/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,493	RICH ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *36-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1.

Claims 1-6, 8-21 and 28-30, are rejected under 35 U.S.C. 102(b) as being anticipated by Hutchens et al., 6,225,047.

As to claims 1, 3, 13, 14, 15, 21,28 and 29, Hutchens et al. disclose an assay method utilizing an adsorbent comprising a polypeptide (col. 5, lines 21-22) and contacting the adsorbent with a sample containing analytes and detecting the retention of adsorbed analytes by desorption spectrometry (col. 18, lines 25-32) such as SELDI (col. 24, lines 46-49) as well as detecting the materials that are unretained on the adsorbent (col. 36, lines 63-67), and wherein eluants include salt concentrations of various concentrations (thus having increasing or decreasing concentrations), (col. 32, lines 2-11), and that the analytes which may be resolved using the disclosed method include fragments of biological macromolecules (col. 34, lines 9-15.) The fragments are deemed to be the claimed first and second components of a multicomponent biological complex.

As to claim 2, the sample is blood (col. 15, lines 8-12.)

As to claim 4, the analyte may be a multimeric molecular complex (col. 5, lines 16-17) and a complex refers to analytes formed by the union of 2 or more analytes (col. 15, lines 1-2.)

As to claims 5 and 6, a receptor is used to bind to a ligand and is subsequently contacted with a sample to detect binding to the ligand (col. 44, lines 21-37.)

As to claim 8, the solid support can be a chromatographic resin (col. 18, lines 34-35.) (Applicants do not define or describe a chromatographic resin in such a way that it excludes the materials used by Hutchens et al.)

As to claims 9 and 10, the washes may be performed in wells (which is a non-flow-through device), (col. 20, lines 13-21.)

As to claims 11 and 12, the washes may be performed in a flow-through column (col. 39, lines 26-46). Column 39, lines 26-46, discloses use of chromatography column for adsorbing the analyte, washing unbound material, and eluting the analyte. While the teaching of analyzing the unbound material is not disclosed in this embodiment using a chromatography column, the general teaching of analyzing unbound material, in addition to the bound material, is disclosed in column 36, lines 63-67, which does not disclose any particular type of solid support and thus it is reasonable to interpret the general teaching to apply to any of the solid supports that are disclosed by the reference in other parts of the reference.)

As to claims 16 and 30, eluants that are different may be used (col. 37, line 66 – col. 38, line 6, disclosing sixteen different selectivity conditions, including different

elution conditions comprising 4 variety of pH levels, 4 variety of ionic strengths, 4 variety of detergent conditions, and 4 variety of hydrophobicity-based conditions.)

As to claim 17, the second component can be detected by optical method (e.g., fluorescence detection), (col. 25, lines 41-44.)

As to claims 18 and 19, the second component can be detected by affinity mass spectrometry (col. 24, lines 55-56.)

As to claim 20, the affinity mass spectrometry comprises SEND (col. 24, line 64.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2.

Claims 22, 23, 25-27 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens et al., 6,225,047.

Hutchens et al. disclose the invention substantially as claimed (see above). More specifically, Hutchens et al. teach that performing the same assays on samples from normal human patients and cancer patients can allow for the identification of potential disease markers (col. 65, lines 31-45.) Hutchens et al. also disclose that varying the

elution characteristics allow for detecting many different types of analytes (col. 32, lines 63-67) as well as improved resolution of the analyte (col. 37, lines 10-14). However, the examples relating to the assays of samples from normal human patients and cancer patients do not appear to utilize different elution characteristics (such as different salt concentrations, col. 32, lines 2-11.)

Nevertheless, given the teachings of the benefits of utilizing different elution conditions (such as varying salt concentrations), it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform assays on the two different samples using different elution conditions such as different salt concentrations because Hutchens et al. teach that utilizing different elution conditions allow for the benefit of detecting many different types of analytes as well as improving resolution of analytes. That is, the skilled artisan would recognize that the benefits of utilizing such different elution conditions in performing an assay on *one* sample would also exist in performing the *two* different assays on a normal sample and a sample from a diseased patient in order to compare and discover potential disease markers. Thus, the skilled artisan would be motivated to vary the elution conditions to detect different analytes or improve resolution of detected analytes in the two different samples for comparison.

As to claim 27, a computerized learning algorithm classifies a profile (col. 7, lines 41-65.)

Limitations of the remaining claims have been discussed above in subsection 1.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens et al., 6,225,047, in view of Morin et al., 6,599,728.

Hutchens et al. disclose the invention substantially as claimed (see above), except for exposing one sample to an inhibitor RNA, and not exposing the other sample to the inhibitory RNA.

However, Hutchens et al. do teach that the analytes may be of various biological materials (col. 34, lines 1-42), and that the eluant may be of various characteristics as desired and can be chosen for a given analyte without the need for undue experimentation (col. 33, lines 12-22), and that the amount detected in the assay is usually compared to a control or standard curve (col. 42, lines 50-52.)

Moreover, Morin et al. teach introducing inhibitory RNA to modulate Tnakyrase II expression in a cell (col. 3, lines 37-43) and that compounds that modulate Tankyrase II can be used to screen random combinatorial libraries of small molecule compounds or as part of rational drug design (col. 20, lines 9-15.) Morin et al. also teach use of positive and negative controls (col. 16, lines 47-50.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the disclosed method wherein the sample is exposed to inhibitor RNA because Morin et al. teach that such a procedure allows for screening for compounds or can be part of a rational drug design. The skilled artisan would have reasonable expectation of success because Hutchens et al. disclose that the eluant may be of various characteristics as desired and can be chosen for a given analyte without the need for undue experimentation. Moreover, it would have been obvious to

the skilled artisan to additionally perform an assay on a sample which is not exposed to inhibitor RNA because such procedures are part of a negative control, as taught by Morin et al. The skilled artisan would recognize that the negative control provides for a means to verify results for accuracy and thus would be motivated to provide such a negative control in the method discussed above.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens et al., 6,225,047, in view of Beutler et al., 5,234,811.

Hutchens et al. disclose the invention substantially as claimed (see above regarding claim 1), except for the affinity molecule being bound to the solid support after binding the complex.

However, Beutler et al. teach that probe/target hybrids may be selectively isolated on a solid matrix, such as hydroxylapatite, which preferentially binds double-stranded nucleic acids. Beutler et al. teach that this is an alternative to immobilizing probe nucleic acids on a solid support and using it to capture target sequences from solution (col. 14, lines 34-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow binding between the double stranded nucleic acid molecules to its target in the Hutchens et al. invention before immobilizing the nucleic acid to a solid support because Beutler et al. teach that probe/target hybrids may be selectively isolated on a solid matrix, such as hydroxylapatite, which preferentially binds double-stranded nucleic acids and that this is an alternative to

immobilizing probe nucleic acids on a solid support before capturing its target. The skilled artisan would have reasonable expectation of success because the end result is the same, i.e., a probe (DNA) bound to a complex (DNA), and thus the skilled artisan would expect that the subsequent procedures taught by Hutchens et al. would also work to elute components for analysis because the components that are bound to the solid support are the same.

Response to Arguments

Applicant's arguments filed May 21, 2007 have been fully considered but are not persuasive. Applicant argues that Hutchens et al. do not teach that the analyte is first retained by the absorbent, then washing the retained analyte, then measuring the wash for presence of an analyte released from the adsorbent. Examiner however finds that this method is encompassed by the elution teachings of Hutchens et al. Column 34, lines 9-15 teaches that analytes that may be resolved include fragments of biological molecules, such as enzymes, proteins, peptides, carbohydrates, and thus the disclosed methods of detecting eluted materials include detecting eluted fragments of immobilized materials.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Y. Lam

Ann Y. Lam
Primary Patent Examiner